UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS END-PAYOR ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL END-PAYOR ACTIONS	Master File No. 1:13-cv-09244-RA-SDA

FOURTH CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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I. INTRODUCTION

1. End-Payor Plaintiffs, United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund, Crosby Tugs, LLC, Insurance Trust Fund, International Union of Operating Engineers Local 132 Health and Welfare Fund, NECA-IBEW Welfare Trust Fund, City of Providence, Rhode Island, Painters District Council No. 30 Health and Welfare Fund, Minnesota and North Dakota Bricklayers and Allied Craftworkers Health Fund, New England Electrical Workers Benefits Fund, MAN-U Service Contract Trust Fund, and 1199SEIU National Benefit Fund (collectively "End-Payor Plaintiffs" or "Plaintiffs") on behalf of themselves and all others similarly situated, file this Fourth Consolidated Amended Class Action Complaint against Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, "Takeda" or "Defendants"). Based upon personal knowledge as to facts pertaining to them, and upon information and belief as to all other matters, the - Plaintiffs allege as follows:

II. NATURE OF THE ACTION

2. This action arises out of Defendants' monopolization and attempted monopolization of the market for pioglitazone hydrochloride tablets, which Takeda sells under the brand name ACTOS. Doctors prescribe ACTOS for the improvement of glycemic control in patients with Type 2 diabetes, as either a monotherapy treatment or a combination therapy consisting of two separate drugs—pioglitazone hydrochloride together with sulfonylurea, metformin, or insulin.

3. ACTOS became one of Takeda's biggest selling products. By 2011, ACTOS generated nearly $3 billion in annual sales. Takeda knew, however, that its product was

vulnerable to a rapid and near-complete loss of sales once less expensive generic versions entered the market.

4. In order to delay the onset of generic competition and squeeze more multi-billion-dollar years out of these products, Takeda submitted false and misleading patent information regarding two patents to the Food and Drug Administration (the "FDA") for publication in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book") with respect to ACTOS. Takeda asserted in its patent information that the two patents—United States Patent Nos. 5,965,584 (the "'584 Patent") and 6,329,404 (the "'404 Patent")—claim the ACTOS drug product. These patents plainly and unambiguously do not claim the ACTOS drug product, however, because the '584 Patent claims a drug product consisting of pioglitazone hydrochloride and a biguanide. Similarly, the '404 Patent claims a drug product consisting of pioglitazone hydrochloride *and* an insulin secretion enhancer.

5. The ACTOS drug product contains neither a biguanide nor an insulin secretion enhancer, and thus neither the '584 Patent nor the '404 Patent claims the ACTOS drug product. Indeed, Takeda has listed the '584 Patent in the Orange Book as claiming the drug product ACTO*plus* met, which does contain both pioglitazone hydrochloride and a biguanide, and has listed the '404 Patent in the Orange Book as claiming the drug product Duetact, which does contain both pioglitazone hydrochloride and an insulin secretion enhancer.

6. Absent Takeda's unlawful conduct, generic competition for ACTOS was likely to begin immediately after ACTOS's drug substance patent—U.S. Patent No. 4,687,777 (the "'777 Patent")—expired on January 17, 2011.

7. Among other intended anticompetitive effects, Takeda's submission of false and misleading patent information regarding the '584 Patent and '404 Patent for ACTOS permitted

the first generic manufacturers that filed an Abbreviated New Drug Application ("ANDA") with a Paragraph IV Certification, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to claim the 180-day exclusivity provided by the Hatch-Waxman Act. That exclusivity prevented the FDA from approving any other generic ACTOS products from entering the market until 180 days after the first filers entered. Takeda's submission of false and misleading patent information thus created a "bottleneck" on FDA approval of *any* generic ACTOS products until the first generic filers entered the market. Later-filing generic manufacturers were automatically delayed due to the first filers' 180-day exclusivity.

8. Takeda's unlawful conduct was designed to and did in fact: (a) delay the entry of less expensive generic versions of ACTOS in the United States; and (b) permit Takeda to maintain a monopoly in the United States for ACTOS and its generic equivalents.

9. Plaintiffs bring this action as a class action on behalf of all consumers and third-party payors (collectively, "End-Payors") in certain States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for branded and/or generic ACTOS products, other than for re-sale, since January 17, 2011 (*see* Class Definition below).

10. Plaintiffs assert claims for compensatory and/or treble damages for violations of the State laws enumerated below.

III. JURISDICTION AND VENUE

11. This Court has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the class exceeds $5,000,000, and at least one member the putative class is a citizen of a state different from that of one of the Defendants.

12. Defendants are subject to personal jurisdiction in this Court, including general and specific jurisdiction.

13. This Court has general jurisdiction over each Defendant because one or more of the Defendants has engaged in such a continuous and systematic course of business in this District as to render it at home in New York, sufficient to satisfy both C.P.L.R. §301 and the requirements of due process. Such course of business includes, but is not limited to:

a. One or more of the Defendants has employees, offices and/or facilities in New York;

b. One or more of the Defendants actively solicits business in and derives substantial sales and revenue from New York;

c. One or more of the Defendants has substantial and ongoing business relationships with New York customers, employees and/or companies; and

d. One or more of the Defendants is registered with the New York Department of State to do business in New York, as a so-called foreign corporation.

14. This Court has specific jurisdiction over each Defendant because one or more of the Defendants purposefully directed its unlawful anticompetitive activities in New York and this lawsuit results from injuries that arise out of and relate to those New York activities, sufficient to satisfy both C.P.L.R. §302 and the requirements of due process.

15. One or more of the Defendants sold the pharmaceutical products at issue in New York at supracompetitive prices, received substantial revenue from the sale of these products in New York, and therefore reaped the benefits of its conduct from New York.

16. One or more of the Defendants agreed to the jurisdiction of this Court in the underlying patent litigations.

17. Venue is appropriate in this district under 28 U.S.C. §1391(b) and (c) because Defendants transact business within this district, and the interstate trade and commerce described herein is carried out, in substantial part, in this district.

IV. PARTIES

A. Plaintiffs

18. Plaintiff United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund ("UFCW Local 1776") is an employee health and welfare benefit plan with its principal place of business at 3031-A Walton Road, Plymouth Meeting, Pennsylvania 19462. Plaintiff UFCW Local 1776 indirectly purchased, paid and/or provided reimbursement for ACTOS in Arizona, Florida, New Jersey, Ohio, Pennsylvania and Virginia other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS other than for re-sale once it became available, at supracompetitive prices during the Class Period, and was thereby injured.

19. Plaintiff Crosby Tugs, LLC ("Crosby Tugs") is a Louisiana limited liability company with its principal place of business in Galliano, Louisiana. Plaintiff Crosby Tugs indirectly purchased, paid and/or provided reimbursement for ACTOS in Louisiana, Maryland, Mississippi and Texas other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS other than for re-sale once it became available, at supracompetitive prices during the Class Period, and was thereby injured.

20. Plaintiff International Union of Operating Engineers Local 132 Health and Welfare Fund ("IUOE Local 132") is an employee welfare benefit plan with its primary office in Huntington, West Virginia. Plaintiff IUEO Local 132 indirectly purchased, paid and/or provided reimbursement for ACTOS in Florida, Illinois, North Carolina, Ohio, Pennsylvania, Texas and

West Virginia other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS other than for re-sale once it became available, at supracompetitive prices during the Class Period, and was thereby injured.

21. Plaintiff NECA-IBEW Welfare Trust Fund ("NECA-IBEW") is an employee welfare benefit plan with its primary office in Decatur, Illinois. Plaintiff NECA-IBEW indirectly purchased, paid and/or provided reimbursement for ACTOS in Alabama, California, Florida, Illinois, Indiana, Kentucky, New Jersey, Nevada, Washington and Wisconsin other than for re-sale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS other than for re-sale once it became available, at supracompetitive prices during the Class Period, and has thereby been injured.

22. Plaintiff City of Providence, Rhode Island ("Providence") is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island. Plaintiff Providence is a self-insured health and welfare plan. Plaintiff Providence indirectly purchased, paid and/or provided reimbursement for ACTOS in Arizona, Connecticut, Florida, Hawaii, Illinois, Maine, Massachusetts, Missouri, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, Texas and Virginia other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of ACTOS other than for re-sale once it became available, at supracompetitive prices during the Class Period, and was thereby injured.

23. Painters District Council No. 30 Health & Welfare Fund ("Painters Fund") is an employee welfare benefit plan with its principal place of business in Aurora, Illinois. Plaintiff Painters Fund indirectly purchased, paid and/or provided reimbursement for ACTOS in Florida, Illinois, Indiana and Pennsylvania other than for resale, and purchased, paid and/or provided

reimbursement for the generic versions of ACTOS other than for re-sale once it became available, at supracompetitive prices during the Class Period, and was thereby injured.

24. Plaintiff Minnesota and North Dakota Bricklayers and Allied Craftworkers Health Fund ("Bricklayers and Allied Craftworkers Fund") is an employee welfare benefit plan, with its principal place of business in Mendota Heights, Minnesota. Plaintiff Bricklayers and Allied Craftworkers Fund indirectly purchased, paid and/or provided reimbursement for ACTOS in Arizona, Florida, Minnesota and Wisconsin other than for re-sale and purchased, paid and/or provided reimbursement for generic versions of ACTOS other than for re-sale once it became available, at supracompetitive prices during the Class Period, and was thereby injured.

25. Plaintiff New England Electrical Workers Benefits Fund ("NEEWBF") is an employee welfare benefit plan with its principal place of business in Wallingford, Connecticut. Plaintiff NEEWBF indirectly purchased, paid and/or provided reimbursement for ACTOS in California, Connecticut, Florida, Massachusetts, Maine, Mississippi, Nebraska, New Hampshire, New Mexico, New York, North Carolina, South Carolina, Tennessee, Texas and Vermont other than for resale and purchased, paid and/or provided reimbursement for generic versions of ACTOS other than for re-sale once it became available, at supracompetitive prices during the Class Period, and was thereby injured.

26. Plaintiff MAN-U Service Contract Trust Fund ("MAN-U") is an employee health and welfare benefit plan trust with its principal place of business at 7130 Columbia Gateway Drive, Suite A, Columbia, MD 21046. Plaintiff MAN-U indirectly purchased and/or provided reimbursement for ACTOS in the District of Columbia, Florida, Illinois, Maryland, Pennsylvania and Virginia other than for re-sale and purchased, paid and/or provided reimbursement for the

generic versions of ACTOS other than for re-sale once it became available at supracompetitive prices, and has thereby been injured.

27. Plaintiff 1199SEIU is an employee health and welfare benefit plan trust with its principal place of business in New York. Plaintiff 1199SEIU indirectly purchased and/or provided reimbursement for ACTOS in Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Indiana, Louisiana, Maryland, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Virginia, District of Columbia and Puerto Rico other than for re-sale and purchased, paid and/or provided reimbursement for the generic versions of ACTOS other than for re-sale once it became available at supracompetitive prices, and has thereby been injured.

B. Defendants

28. Defendant Takeda Pharmaceutical Company Limited is a Japanese company with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645.

29. Defendant Takeda America Holdings, Inc. is a wholly-owned subsidiary of Defendant Takeda Pharmaceutical Company Limited, and is the United States parent corporation of Defendants Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. Defendant Takeda America Holdings, Inc. is a corporation organized under the laws of the State of New York with its principal place of business at 767 Third Avenue, New York, New York 10017.

30. Defendant Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

31. Defendant Takeda Development Center Americas, Inc., formerly known as Takeda Global Research and Development Center, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

32. The foregoing Defendants will collectively be referred to as "Takeda" or "Defendants."

V. INDUSTRY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs, Listing Patent Information in the Orange Book, and the Substitution of Generic Drugs for Brand Name Drugs

33. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), branded drug manufacturers must obtain FDA approval to sell a new drug product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301–392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on any applicable patents. 21 U.S.C. § 355(a), (b).

34. When the FDA approves a branded drug manufacturer's NDA, the manufacturer may list in the Orange Book any patents the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the branded drug before the expiration of the listed patents. The branded drug manufacturer may also list in the Orange Book any patents issued after the FDA approved the NDA within thirty days of their issuance. 21 U.S.C. § 355(b)(1) & (c)(2).

35. The FDA relies completely on a branded drug manufacturer's truthfulness about patent validity and applicability because the FDA does not have the resources or authority to verify a branded drug manufacturer's patents and patent information for accuracy or

trustworthiness. In listing patents and patent information in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

36. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in a branded drug manufacturer's original NDA, but must further show that the generic drug (i) contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and (ii) is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

37. The FDCA and Hatch-Waxman Act operate on the presumption that bioequivalent drugs containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence means that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as its branded counterpart. 21 U.S.C. § 355(j)(8)(B).

38. Congress enacted the Hatch-Waxman Act to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also

sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

39. The Hatch-Waxman Act achieved both goals by advancing substantially the rate of generic product launches and ushering in an era of historic high profit margins for branded drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total annual prescription drug revenue had soared to $300 billion.

2. Requirements for Submitting Patent Information

40. The regulatory structure created by the Hatch-Waxman Act includes a process for identifying and addressing patents that arguably apply to brand and generic drug products. This regulatory structure requires the holder of an NDA to submit information concerning its patents to the FDA, which incorporates the information into the Orange Book. Patent information is listed in the Orange Book for each NDA to which the patent may apply. Then, when a generic company seeks to file an ANDA, it must submit patent certifications or statements, described more fully below, to each patent listed in the Orange Book for the NDA that is the reference listed drug for the ANDA.

41. Under the Hatch-Waxman Act, the NDA holder must submit certain required information concerning "any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

42. When Takeda submitted patent information regarding the '584 Patent and '404 Patent for ACTOS—in 1999 and 2002, respectively—the relevant statute required the NDA applicant to list "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C.A. § 355(b)(1) (1999) & (2002).

43. The then-applicable regulations identified three types of patents that could properly be listed: "drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents." 21 C.F.R. § 314.53(b) (1999) & (2002). The regulations further provided that "[f]or patents that claim a drug substance or drug product, the [NDA] applicant shall submit information only on those patents that *claim a drug product that is the subject of a pending or approved application*, or that claim a drug substance that is a component of such a product." *Id.* (emphasis added). The NDA holder also could properly list a patent for a drug product only "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale *of the drug product*." *Id.* (emphasis added). In short, for patents that claimed a drug product, the NDA applicant could submit information describing the patent as a "drug product patent" only if the patent claimed the drug product that was the subject of the NDA; the patent's drug-product claim could claim not just *some* drug product—it had to claim the *relevant* drug product, *i.e.*, the FDA approved drug product as to which the NDA applicant listed the patent.

44. NDA applicants were on their honor to properly identify the "Type of patent, *i.e.*, drug, drug product, or method of use." 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002). The FDA

expressly refused to police the proper listing of patents and patent information, noting that it "does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA," and that it "believes that the declaration requirements under § 314.53(c) [requiring the applicant to declare "that Patent No. ____ covers the formulation, composition, and/or method of use of (name of drug product)"], as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted." *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343-45 (Oct. 3, 1994).

45. Important regulatory and competitive consequences flow from the distinction between patents described as containing relevant drug-product claims, and patents described as containing only method-of-use claims. If the patentee describes the patent in the patent information as containing a relevant drug-product claim, an ANDA applicant desiring to market its generic product before the patent expires must file a Paragraph IV Certification, certifying that the patent is invalid, unenforceable, or would not be infringed by the generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). The patentee and/or NDA holder then has the opportunity to obtain an automatic 30-month stay on generic competition by filing a patent infringement lawsuit against the ANDA applicant. In addition, and of particular importance here, the FDA is prohibited from approving a subsequent applicant's ANDA until 180 days after the first filer has entered the market. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity creates a "bottleneck" that delays *all* generic competition until 180 days after the first filer enters the market.

46. By contrast, if the patentee describes the patent as containing only relevant method-of-use claims, in certain circumstances an ANDA applicant can submit what is known as

a "Section viii Statement." 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii). In a Section viii Statement, the ANDA applicant states that it is not seeking approval for the particular use covered by the method-of-use patent. If an ANDA applicant makes only a Section viii Statement, then the patentee or NDA holder *cannot* obtain an automatic 30-month stay on generic competition even if it sues the ANDA applicant for patent infringement. And the FDA can approve an ANDA containing only a Section viii Statement *without regard* to whether any other ANDA applicant is otherwise entitled to a 180-day exclusivity period.

47. Whether a patent actually claims the relevant drug product is irrelevant for purposes of Paragraph IV Certifications. Rather, FDA regulations and instructions made unmistakably clear that the *patent information* submitted by the NDA applicant determined whether generic manufacturers would be permitted to make Paragraph IV Certifications and thus would be eligible for the 180-day exclusivity period. *See*, for example, FDA Proposed Rule, *Abbreviated New Drug Application Regulations*, 54 FR 28872, at 28885 (July 10, 1989) ("the patent information submitted to FDA, whether or not published in the list, should be the basis of the [generic company's] certification"); 21 C.F.R. § 314.94(a)(12)(iii) (ability to submit only a Section viii Statement is based on "patent information … submitted under … § 319.53").

48. In short, describing a patent as containing a relevant drug-product claim gives the patentee two key competitive advantages—an automatic 30-month stay on generic competition, and a bottleneck that delays all generic competition until 180 days after the first generic filer enters the market.

3. Paragraph IV Certifications

49. Where the NDA holder has submitted patent information describing a listed patent as claiming a relevant drug substance or drug product, an ANDA applicant must certify

that the generic drug will not infringe those patents. Under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the branded drug has been filed with the FDA (a "Paragraph I Certification");

ii. that the patent for the branded drug has expired (a "Paragraph II Certification");

iii. that the patent for the branded drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III Certification"); or

iv. that the patent for the branded drug is invalid or will not be infringed by the generic drug manufacturer's proposed product (a "Paragraph IV Certification").

50. If a generic drug manufacturer files a Paragraph IV Certification, a branded drug manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the branded drug manufacturer initiates a patent infringement action against the generic drug manufacturer filer within forty-five days of receiving notification of the Paragraph IV Certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic drug manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic drug manufacturer to market its product. FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

51. As an incentive to generic drug manufacturers to seek approval of generic alternatives to branded drugs, the first generic drug manufacturer to file an ANDA containing a Paragraph IV Certification typically receives a period of protection from competition from other generic versions of the drug. For Paragraph IV Certifications made before December 8, 2003,

the first generic drug manufacturer applicants received 180 days of market exclusivity, which could not be forfeited and was triggered only by commercial marketing of the generic product. For Paragraph IV Certifications made after December 8, 2003, the first generic drug manufacturer applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means the first approved generic drug is the only available generic drug for at least six months.

52. Branded drug manufacturers can "game the system" by describing patents as containing relevant drug-product claims (even if the patents, in fact, do not do so) and suing any generic drug manufacturer competitor filing an ANDA with a Paragraph IV Certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That branded drug manufacturers often sue generic drug manufacturers under Hatch-Waxman simply to delay generic drug competition—as opposed to enforcing a valid patent that is actually infringed by the generic drug—is demonstrated by the fact that generic drug manufacturers have prevailed in Paragraph IV Litigation in cases involving 73% of the drug products studied—either by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal of the suit.

53. For Paragraph IV Certifications made before December 8, 2003, the first generic drug manufacturer applicant could help a branded drug manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic drug manufacturers. In exchange for payments from the branded drug manufacturer, the first generic drug manufacturer applicant could agree to delay marketing its generic drug, thereby extending the 180-day exclusivity bottleneck.

B. The Benefits of Generic Drugs

54. Generic versions of branded drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their branded counterparts. The only material difference between generic drugs and branded drugs is their price: generic drugs are usually at least 25% less expensive than their branded drug counterparts when there is a single generic drug competitor. The discount typically increases to 50% to 80% (or more) when there are multiple generic drug manufacturer competitors in the market for a given branded drug. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales at 15% of the price of the branded drug. As a result, competition from generic drugs is viewed by branded drug manufacturers, such as Takeda, as a grave threat to their bottom lines.

55. Due to the price differentials between branded and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the branded drug. Since passage of the Hatch-Waxman Act, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for branded drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

56. There is an incentive to choose the less expensive generic drug equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generic drugs than on branded drugs. Private health insurers similarly offer direct incentives to pharmacies to

substitute cheaper generic drugs for more expensive branded drugs. Health insurers are contractually obligated to pay for the bulk of their insureds' prescriptions, whether filled with branded drugs or generic drugs, so they offer lower copays for generic drugs in order to encourage their use.

57. Generic drug competition enables all putative Class members to (i) purchase generic versions of a drug at substantially lower prices; and/or (ii) purchase a branded drug at a reduced price.

58. Until the generic version of a branded drug enters the market, however, there is no bioequivalent generic drug to substitute for, and compete with, the branded drug, and, therefore, the branded drug manufacturer can continue to profitably charge supracompetitive prices. As a result, brand drug manufacturers, such as Takeda, which are well aware of the rapid erosion of branded drug sales by generic drugs, have a strong incentive to delay the introduction of generic drug competition into the market, including through tactics such as the improper patent listing and Exclusion Payment Agreements.

C. The Impact of Authorized Generics

59. The 180-day marketing exclusivity to which first-filer generic drug manufacturers may be entitled does not prevent a branded drug manufacturer from marketing its own generic drug alternative to the branded drug during the 180-day period. Such an "authorized generic" is chemically identical to the branded drug, but is sold as a generic drug through either the branded manufacturer's subsidiary (if it has one) or through a third-party generic drug manufacturer. Competition from an authorized generic drug during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

60. In its recent study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the FTC found that authorized generic drugs capture a significant portion of sales, reducing the first-filer generic drug manufacturer's revenues by approximately half on average during the 180-day exclusivity period. The first-filing generic drug manufacturer makes significantly less money when it faces competition from an authorized generic because (i) the authorized generic drug takes a large share of unit sales away from the first filer; and (ii) the presence of an additional generic drug in the market causes prices to decrease.

61. Although first-filing generic drug manufacturers make significantly less money when they must compete with an authorized generic drug during the first 180 days, consumers and other drug purchasers, such as Plaintiffs and members of the putative End-Payor Class, benefit from the lower prices caused by competition between the authorized generic drug manufacturer and the first-filing generic drug manufacturer.

VI. TAKEDA'S ANTICOMPETITIVE CONDUCT

62. On January 15, 1999, Takeda submitted to the FDA NDA 21-073, seeking approval to manufacture, market, and sell ACTOS, which contains the active ingredient pioglitazone hydrochloride, and is used to improve glycemic control in adults with Type 2 diabetes when diet and exercise are not sufficient. On July 15, 1999, the FDA approved Takeda's NDA for the use of ACTOS to improve glycemic control in adults with Type 2 diabetes—either as monotherapy or in combination with a sulfonylurea, metformin, or insulin.

63. Pursuant to the FDA's requirements, Takeda submitted the '777 Patent, entitled "Thiazolidinedione Derivatives, Useful As Antidiabetic Agents," for listing in the Orange Book as a drug substance patent covering ACTOS. The '777 Patent claims the active ingredient for

ACTOS, pioglitazone hydrochloride, and was issued to inventors Kanji Meguro and Takeshi Fujita on August 18, 1987, and assigned to Takeda. The '777 Patent purports to claim the novel compound commonly known under the nonproprietary name "pioglitazone" and its pharmacologically acceptable salts. ACTOS is covered by the '777 Patent, which expired on January 17, 2011.

64. As stated previously, Takeda knew its blockbuster drug would suffer from generic competition upon expiration of the '777 Patent. In order to extend its patent monopoly beyond January 17, 2011, Takeda knowingly and falsely represented to the FDA that the '584 and '404 patents are something they are not—drug-product patents that claim the ACTOS drug product.

65. The '584 Patent, entitled "Pharmaceutical Composition," purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* a biguanide (*e.g.*, metformin) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide (*e.g.*, metformin). Takeda is the owner, by assignment, of the '584 Patent, which expired on June 19, 2016. Takeda knew that the '584 patent did not claim the ACTOS drug product, but only a method of using it. ACTO*plus* met, not ACTOS, is the purported commercial embodiment of the '584 Patent. Nevertheless, Takeda submitted patent information to the FDA describing the '584 Patent as a drug-product patent *that claims ACTOS*. When submitting the '584 Patent information to the FDA, Takeda knew that the information was false and misleading, and Takeda acted with the purpose and effect of impairing competition from generic drugs.

66. The '404 Patent, entitled "Pharmaceutical Composition," purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* an insulin secretion enhancer (*e.g.*, a sulfonylurea, such as glimepiride) and methods for treating

diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer. Takeda is the owner, by assignment, of the '404 Patent, which expired on June 19, 2016. Takeda knew that the '404 patent did not claim the ACTOS drug product, but only a method of using it. Duetact, not ACTOS, is the purported commercial embodiment of the '404 Patent. Nevertheless, Takeda submitted patent information to the FDA describing the '404 Patent as a drug-product patent *that claims ACTOS*. When submitting the '404 Patent information to the FDA, Takeda knew that the information was false and misleading, and Takeda acted with the purpose and effect of impairing competition from generic drugs.

67. In addition to the '777 Patent, the '584 Patent, and the '404 Patent, Takeda submitted eight other patents to the FDA for listing in the Orange Book. These patents (the "Method-of-Use Patents") claimed various methods of using ACTOS in combination with other drug products (such as biguanide or an insulin secretion enhancer) to treat various conditions or to reduce various side effects. Takeda listed the Method-of-Use Patents in the Orange Book as method-of-use patents, not drug-substance or drug-product patents.

68. Under both the Hatch-Waxman Act and the FDA's implementing regulations, the drug-product claims of the '584 Patent and the '404 Patent do not form a permissible basis for Takeda to submit patent information describing the patents as drug-product patents covering ACTOS.

69. *First*, Takeda could properly identify the '584 Patent and the '404 Patent as drug-product patents claiming ACTOS only if the patents in fact claimed the ACTOS drug product. The patents unequivocally do not do so. The *only* active ingredient in ACTOS is pioglitazone hydrochloride. By contrast, the drug-product claims in the '584 Patent and the '404 Patent claim

drug products containing *both* pioglitazone *and* certain additional active ingredients—a biguanide or an insulin secretion enhancer, respectively. Neither patent claims a drug product that contains pioglitazone as its sole active ingredient. Thus, the patents do not claim the ACTOS drug product as a matter of law.

70. *Second*, Takeda could not reasonably assert the drug-product claims of the '584 Patent or the '404 Patent against generic drug manufacturers seeking to market ACTOS. The patents claimed only drugs *other* than the ACTOS drug product. In fact, it would be impossible for any ANDA referencing the ACTOS NDA to get FDA approval of a drug containing either of the compositions claimed in the '584 and '404 Patents. Moreover, as noted in further detail below, although Takeda originally asserted those drug-product claims against generic drug manufacturers of ACTOS, Takeda withdrew the claims before a court could rule on them—but only after the generic drug manufacturers had made their Paragraph IV Certifications against those two patents.

71. Nevertheless, on or about November 5, 1999, Takeda submitted patent information stating that the '584 Patent claimed both the "drug product" ACTOS and its "method of use." Similarly, on or about January 3, 2002, Takeda submitted patent information stating that the '404 Patent claimed both the "Drug Product" ACTOS and its "Method of Use." Takeda submitted the patent information knowing that it was false and misleading, and Takeda submitted that information with the purpose and effect of impairing competition from generic drugs.

72. In response to a citizen petition submitted to the FDA by Sandoz, Inc. ("Sandoz"), Teva Pharmaceuticals USA, Inc. ("Teva") asserted that Takeda had improperly caused the FDA to list the '584 Patent and '404 Patent in the Orange Book as drug-product patents for ACTOS. In its comment to the citizen petition, dated January 22, 2010, Takeda "confirm[ed] for FDA the

listing of [the '584 Patent and '404 Patent] under the terms described in Takeda's original patent submissions." Takeda further acknowledged that it "characterized them for FDA in the appropriate patent declarations as containing both 'Drug product' and 'Method of use' claims," and that "[s]ince the original submission of these patents to FDA, Takeda has continued to certify to the applicability of the patents to ACTOS under the original declarations…."

73. In a ruling on Sandoz's citizen petition, dated March 15, 2010, the FDA confirmed that Takeda's original patent information had indeed "stated that the patents claimed both the drug product and a method of use." The FDA further concluded that "[i]n keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA." The FDA specifically noted that Takeda's January 22, 2010 comment to the citizen petition had "reconfirm[ed]" the original listing. Moreover, "FDA's role in listing patents and patent information in the Orange Book is ministerial," and "FDA relies on the NDA sponsors to provide an accurate patent submission."

74. The FDA concluded that, because Takeda had submitted patent information describing the '584 Patent and '404 Patent as claiming the ACTOS drug product, all ANDA filers seeking approval to market generic ACTOS before the expiration of the patents were required to submit Paragraph IV Certifications, rather than Section viii Statements, with respect to them. The requirement that Teva and all ANDA filers submit Paragraph IV Certifications—and thereby become subject to the first filers' 180-exclusivity—resulted from Takeda's description of the '584 Patent and '404 Patent as drug-product patents claiming ACTOS: the FDA concluded that, "[I]t is the patent declaration submitted by the NDA holder and any subsequent amendments or supplements to that declaration that controls FDA's listing of patents

and patent information. In keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA."

VII. ANTICOMPETITIVE EFFECTS

75. But for the anticompetitive conduct alleged above, generic competition for ACTOS would have begun earlier, and as early as January 17, 2011, when the '777 Patent expired.

76. Following its March 15, 2010 decision on Sandoz's citizen petition, the FDA conditioned every generic manufacturer's final approval, none of which had yet been granted, on the generic properly addressing Takeda's patents in light of how Takeda characterized them to the FDA.

77. Had Takeda acted lawfully, it would have properly characterized the '584 and '404 Patents to the FDA in 1999 and 2002 as only "method-of-use patents," claiming methods of using ACTOS in combination therapy—and not as "drug-product patents" claiming the ACTOS product itself.

78. Had Takeda properly characterized its patents, the FDA's decision on Sandoz's citizen petition would have required all ACTOS generic manufacturers, as a condition to receiving final approval, to address the '584 and '404 Patents only as method-of-use patents—using *either* a Section viii Statement *or* a Paragraph IV Certification, *not both*. Thus, to the extent any existing or subsequent ACTOS ANDA filers addressed the '584 and '404 Patents with split certifications—Paragraph IV Certifications as to the Patents' combination drug-product claims and Section viii Statements as to the Patents' method-of-use claims—the FDA would

have withheld their approvals until they amended their ANDAs to address the '584 and '404 Patents properly.

79. Accordingly, absent Takeda's false patent descriptions, each of the ACTOS generics with ANDAs containing split certifications and pending at the time of the FDA's decision on Sandoz's citizen petition would have amended their ANDAs to address each of the '584 and '404 Patents as only method-of-use patents, using either a Section viii Statement or Paragraph IV Certification, not both.

80. Moreover, absent Takeda's false patent descriptions, the ACTOS generic manufacturers that made split certifications only after the FDA's decision on Sandoz's citizen petition would have never filed ANDAs addressing the '584 or '404 Patents in such a way. From the time of their initial ANDA filing, they would have chosen to address each of the '584 and '404 Patents as only method-of-use patents, using either a Section viii Statement or Paragraph IV Certification, not both.

81. As rational profit maximizing entities, all generic applicants faced with the choice of addressing the Patents' method-of-use claims with either Paragraph IV Certifications or Section viii Statements would have elected Section viii Statements exclusively. Making a Paragraph IV Certification subjects the manufacturer to Paragraph IV litigation, erecting the 30-month and possibly the 180-day entry barrier. Moreover, relying on a Paragraph IV Certification to address the Patents' method-of-use claims would have made a defense to Takeda's induced-infringement claims more difficult. The purpose of Section viii is to permit generic manufacturers facing only method-of-use claims to avoid those barriers and thereby quickly come to market. In fact, all of the generic manufacturers *did* make only Section viii Statements with respect to the Patents' method-of-use claims.

82. The details of the generic manufacturers' ANDA filings, and the effect of Takeda's false patent descriptions on those manufacturers' entry into the market, are set forth below.

83. Mylan Pharmaceuticals, Inc. ("Mylan"), Watson Pharmaceuticals, Inc. ("Watson"), and Ranbaxy Laboratories, Inc. ("Ranbaxy") each filed their ANDAs on July 15, 2003—the earliest day permitted under the statute. Because they were the first ANDAs filed containing a Paragraph IV Certification, they were entitled to "shared" 180-day exclusivity with respect to generic ACTOS. Alphapharm was also a first filer for generic ACTOS and its ANDA addressed the '584 and '404 Patents, as well as the Method-of-Use Patents, exclusively with Section viii Statements. Mylan subsequently acquired Alphapharm in 2007.

84. Mylan submitted ANDA 76801 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Mylan submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Mylan submitted Section viii Statements. With respect to the '777 Patent, Mylan originally submitted a Paragraph IV Certification, eventually amending to a Paragraph III Certification. Mylan thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011.

85. By letter dated September 8, 2003, Mylan notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Mylan had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on September 11, 2003 and sued Mylan on October 17, 2003. *Takeda Chemical Indus., Ltd., et. al. v. Mylan Labs., Inc.*, 03-cv-8253 (S.D.N.Y.). Mylan's thirty-month stay accordingly expired on March 11, 2006.

86. On or around March 15, 2010, the day the FDA decided Sandoz's citizen petition, Mylan settled the lawsuit with Takeda. Given that Mylan had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, Mylan agreed to withdraw its Section viii Statements and delay entry until the earlier of August 17, 2012 or the date another generic version of ACTOS enters the market. A generic manufacturer that has 180-day exclusivity makes during that exclusivity period more than 80% of all of the profit that it will ever make on the drug. A generic manufacturer that has 180-day exclusivity will therefore settle for a later entry date and other terms than it would have absent the claim to 180-day exclusivity, which is what Mylan did as a result of Takeda's conduct.

87. On November 3, 2004, the FDA awarded Mylan's ANDA tentative approval. On August 17, 2012, Mylan's ANDA received final approval from the FDA and Mylan entered the market with its generic ACTOS on or around that same day. Absent Takeda's conduct, Mylan's ANDA was, or would have been, approvable as early as January 17, 2011. Mylan did not push for approval before August 17, 2012, and the FDA did not grant approval before then, because the FDA's practice is not to grant approval until on or near the generic's agreed entry date where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement.

88. Absent Takeda's conduct, Mylan would have entered the market sooner than it did, as early as January 17, 2011.

89. Watson submitted ANDA 76798 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Watson submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Watson submitted Section viii Statements. With respect to the '777 Patent, Watson

submitted a Paragraph III Certification. Watson thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011.

90. By letter dated September 9, 2003, Watson notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Watson had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on September 12, 2003 and sued Watson on October 11, 2003. *Takeda Chemical Indus., Ltd., et. al. v. Watson Labs., Inc.*, 03-cv-8254 (S.D.N.Y.). Watson's thirty-month stay accordingly expired on March 12, 2006.

91. On or around March 9, 2010, Watson settled the lawsuit with Takeda. Given that Watson had 180-day exclusivity as a result of Takeda's November 5, 1999 and January 3, 2002 false descriptions of the '584 and '404 Patents, Watson agreed to withdraw its Section viii Statements and delay entry until the earlier of August 17, 2012 or the date another generic version of ACTOS enters the market. As noted above, a generic manufacturer that has 180-day exclusivity will therefore settle for a later entry date and other terms than it would have absent the claim to 180-day exclusivity, which is what Watson did as a result of Takeda's conduct.

92. On December 13, 2005, the FDA awarded Watson's ANDA tentative approval. On August 23, 2012, the FDA provided Watson another tentative approval letter, stating that Watson's March 7, 2012 ANDA amendment, which had re-certified under Paragraph IV, rendered Watson ineligible for 180-day exclusivity. Watson sued the FDA and obtained a court order requiring the FDA to grant Watson's ANDA final approval effective immediately. *Watson Labs, Inc. v. Sebelius*, 12-cv-01344 (D.D.C. Oct. 22, 2012). On October 26, 2012, Watson's ANDA received final approval from the FDA and Watson entered the market with that product on or around that same day. Absent Takeda's conduct, Watson's March 7, 2012 ANDA

amendment and ensuing litigation with the FDA would not have occurred or, alternatively, would have occurred and been resolved earlier, and thus Watson would have received final FDA approval earlier than October 26, 2012, and as early as January 17, 2011.

93. Absent Takeda's conduct, Watson would have entered the market sooner than it did, as early as January 17, 2011.

94. Ranbaxy submitted ANDA 76800 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Ranbaxy submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Ranbaxy submitted Section viii Statements. With respect to the '777 Patent, Ranbaxy submitted a Paragraph III Certification. Ranbaxy thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011.

95. By letter dated September 18, 2003, Ranbaxy notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Ranbaxy had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on September 22, 2003 and sued Ranbaxy on October 17, 2003. *Takeda Chemical Indus., Ltd., et. al. v. Ranbaxy Labs., Ltd. et. al.*, 03-cv-8250 (S.D.N.Y.). Ranbaxy's thirty-month stay accordingly expired on March 22, 2006.

96. On or around March 9, 2010, Ranbaxy settled the lawsuit with Takeda. Given that Ranbaxy had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, Ranbaxy agreed to withdraw its Section viii Statements and delay entry until the earlier of August 17, 2012 or the date another generic

version of ACTOS entered the market, with an option to market an authorized generic version of ACTOS supplied by Takeda. As noted above, a generic manufacturer that has 180-day exclusivity will therefore settle for a later entry date and other terms than it would have absent the claim to 180-day exclusivity, which is what Ranbaxy did as a result of Takeda's conduct.

97. Absent Takeda's conduct, Ranbaxy would have entered the market sooner than it did, as early as January 17, 2011.

98. Teva submitted ANDA 77210 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Teva submitted Section viii Statements addressing the Patents' method-of-use claims and did not address the Patents' drug-product claims. With respect to the Method-of-Use Patents, Teva submitted Section viii Statements. With respect to the '777 Patent, Teva submitted a Paragraph III Certification. Teva thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011.

99. Because Teva's ANDA contained no Paragraph IV Certification, Teva did not provide Takeda a Paragraph IV notice letter pursuant to 21 U.S.C. § 355(j)(2)(B), and Takeda did not initially sue Teva for patent infringement. On December 30, 2008, Teva filed ANDA 91155, referencing for approval another Takeda other drug product ACTO*plus* met. Teva's ANDA 91155 contained a Paragraph IV Certification to the '584 Patent and certain other ACTO*plus* met patents. On May 18, 2009, in response to Teva's Paragraph IV Certification, Takeda initiated suit relating to both Teva's ANDA 77210 and Teva's ANDA 91155. *Takeda Pharmaceutical Company Limited et. al. v. Teva Pharmaceutical Industries Ltd. et. al.*, 09-cv-4665 (S.D.N.Y.).

100. On or around December 21, 2010, Teva settled the lawsuit with Takeda. Given that Mylan, Watson, and Ranbaxy agreed to delay entry until August 17, 2012, and given that Mylan, Watson, and Ranbaxy had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, Teva agreed to withdraw all its Section viii Statements and settle the lawsuit by accepting a license to market an authorized-generic version of ACTOS on the earlier of August 17, 2012 or the date another generic version of ACTOS enters the market, as well as an option to enter the market with Teva's own ANDA 77210 product on February 13, 2013.

101. On February 7, 2006, Teva's ANDA 77210 received tentative FDA approval. Teva commenced marketing as an authorized generic for ACTOS on August 17, 2012. On January 10, 2014, Teva's ANDA 77210 received final approval from the FDA. On or around February 4, 2015, Teva commenced marketing of its ANDA 77210 product. Teva's ANDA 77210 was, or would have been, ready for final approval on January 17, 2011. Teva did not push for approval before January 10, 2014, and the FDA did not grant approval before then, because the FDA's practice is not to grant approval where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement and intended to begin marketing as an authorized generic.

102. Absent Takeda's conduct, Teva's ANDA 77210, containing Section viii Statements to the '584 and '404 patents, would have remained eligible for final FDA approval following the FDA's decision on Sandoz's Citizen Petition, eliminating the need for Teva to demand, and Takeda to provide, a license for Teva to market an authorized generic.

103. Absent Takeda's conduct, Teva would have begun marketing an ACTOS generic under its ANDA 77210 much sooner than August 17, 2012, as early as January 17, 2011.

Following the FDA's decision on Sandoz's Citizen Petition, Teva sought to correct or delete Takeda's false listing, stating:

> The consequence of those incorrect listings – and the resulting directive by FDA that ANDA applicants must file paragraph IV certifications – will likely cause a substantial delay of approximately *two years* in FDA's approval for Teva's ANDA, from January 2011 (the expiration date of the drug substance patent covering pioglitazone) to February 2013 (the date on which any 180-day exclusivity would expire if first-filers launch in the August 2002 timeframe evidently specified in their settlements with Takeda). In addition, Takeda's wrongful conduct likely will mean that there will be *no* generic version of Actos® available to consumers for more than 18 months after such products otherwise would be available.

104. As a profit-maximizing entity, Takeda would have responded to Teva's market entry by marketing Takeda's own authorized generic in competition with Teva and every other ACTOS ANDA filer.

105. Sandoz submitted ANDA 078670 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Sandoz submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Sandoz submitted Section viii Statements. With respect to the '777 Patent, Sandoz submitted a Paragraph III Certification. Sandoz thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011.

106. By letter dated April 3, 2007, Sandoz notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Sandoz had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on April 6, 2007 and sued Sandoz on May 16,

2007. *Takeda Pharmaceutical Company Limited et. al. v. Sandoz Inc.*, 07-cv-03844 (S.D.N.Y.). Sandoz's thirty-month stay accordingly expired on October 6, 2009.

107. On or around April 2010, Sandoz settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, and given that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, Sandoz agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

108. On February 13, 2013, Sandoz's ANDA received final approval from the FDA and Sandoz entered the market with that product on or around that same day. Sandoz's ANDA was, or would have been, approvable as early as January 17, 2011. Sandoz did not push for approval before February 13, 2013, and the FDA did not grant approval before then, because the FDA's practice is not to grant approval until on or near the generic's agreed entry date where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement.

109. Absent Takeda's conduct, Sandoz would have entered the market sooner than it did, as early as January 17, 2011.

110. Torrent Pharmaceuticals Ltd. ("Torrent") submitted ANDA 091298 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Torrent submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Torrent submitted Section viii Statements. With respect to the '777 Patent, Torrent submitted a Paragraph III Certification. Torrent thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011. By letter dated May 30,

2009, Torrent notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Torrent had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on June 3, 2009 and sued Torrent on July 2, 2009. *Takeda Pharmaceutical Company Limited et. al. v. Torrent Pharmaceuticals Ltd. et al.*, 09-cv-06051 (S.D.N.Y.). Torrent's thirty-month stay accordingly expired on December 3, 2011.

111. On or around April 2010, Torrent settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Torrent was subject to a 30-month stay that did not expire until December 3, 2011, Torrent agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

112. On February 13, 2013, Torrent's ANDA received final approval from the FDA and Torrent entered the market with that product on or around that same day. Torrent's ANDA was, or would have been, approvable as early as January 17, 2011. Torrent did not push for approval before February 13, 2013, and the FDA did not grant approval before then, because the FDA's practice is not to grant approval until on or near the generic's agreed entry date where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement.

113. Absent Takeda's conduct, Torrent would have entered the market sooner than it did, as early as January 17, 2011.

114. Aurobindo Ltd. ("Aurobindo") submitted ANDA 200268 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Aurobindo submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With

respect to the Method-of-Use Patents, Aurobindo submitted Section viii Statements. With respect to the '777 Patent, Aurobindo submitted a Paragraph III Certification. Aurobindo thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011. By letter dated December 2, 2009, Aurobindo notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Aurobindo had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on December 7, 2009 and sued Aurobindo on January 13, 2010. *Takeda Pharmaceutical Company Limited et. al. v. Aurobindo Ltd.*, 10-cv-00247 (S.D.N.Y.). Aurobindo's thirty-month stay accordingly expired on June 7, 2012.

115. On or around May 2010, Aurobindo settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Aurobindo was subject to a 30-month stay that did not expire until June 7, 2012, Aurobindo agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

116. On February 13, 2013, Aurobindo's ANDA received final approval from the FDA and Aurobindo entered the market with that product on or around that same day. Aurobindo's ANDA was, or would have been, approvable as early as January 17, 2011. Aurobindo did not push for approval before February 13, 2013, and the FDA did not grant approval before then, because the FDA's practice is not to grant approval until on or near the generic's agreed entry date where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement.

117. Absent Takeda's conduct, Aurobindo would have entered the market sooner than it did, as early as January 17, 2011.

118. Dr. Reddy's Laboratories, Inc. ("DRL") submitted ANDA 078383 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, DRL submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, DRL submitted Section viii Statements. With respect to the '777 Patent, DRL submitted a Paragraph III Certification. DRL thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011. By letter dated April 6, 2010, DRL notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that DRL had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on April 9, 2010 and sued DRL on May 20, 2010. *Takeda Pharmaceutical Company Limited et. al. v. Dr. Reddy's Laboratories, Inc.*, 10-cv-04168 (S.D.N.Y.). DRL's thirty-month stay accordingly expired on October 9, 2012.

119. On or around August 2010, DRL settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that DRL was subject to a thirty-month stay that did not expire until October 9, 2012, DRL agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

120. On March 12, 2013, DRL's ANDA received final approval from the FDA. DRL's ANDA was, or would have been, approvable as early as January 17, 2011. DRL did not

push for approval before February 13, 2013, and the FDA did not grant approval before then, because the FDA's practice is not to grant approval until on or near the generic's agreed entry date where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement.

121. Absent Takeda's conduct, DRL would have entered the market sooner than it did, on a date to be proved at trial.

122. Macleods Pharmaceuticals Limited ("Macleods") submitted ANDA 202467 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Macleods submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Macleods submitted Section viii Statements. With respect to the '777 Patent, Macleods submitted a Paragraph III Certification. Macleods thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011. By letter purportedly dated April 18, 2010, Macleods notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Macleods had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on April 19, 2011 and sued Macleods on May 6, 2011. *Takeda Pharmaceutical Company Limited et. al. v. Macleods Pharmaceuticals Ltd.*, 11-cv-03109 (S.D.N.Y.). Macleods' thirty-month stay accordingly expired on October 19, 2013.

123. On or around June 2011, Macleods settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Macleods was subject to a thirty-month stay that did not expire until

October 19, 2013, Macleods agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

124. The FDA awarded Macleods' ANDA tentative approval on September 26, 2012. On February 6, 2013, Macleods' ANDA received final approval from the FDA—a week before expiration of the first filers' 180-day exclusivity period because one of the first filers selectively waived its rights to 180-day exclusivity vis-à-vis Macleods effective on February 6, 2012. Macleods entered the market with that product on or around when it received final approval. Macleods' ANDA was, or would have been, approvable as early as January 17, 2011. Macleods did not push for approval before February 13, 2013, and the FDA did not grant approval before then, because the FDA's practice is not to grant approval until on or near the generic's agreed entry date where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement.

125. Absent Takeda's conduct, Macleods would have entered the market sooner than it did, on a date to be proved at trial.

126. Wockhardt USA LLC or its affiliates ("Wockhardt") submitted ANDA 078038 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Wockhardt submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Wockhardt submitted Section viii Statements. With respect to the '777 Patent, Wockhardt submitted a Paragraph III Certification. Wockhardt thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011. By letter dated June 16, 2010, Wockhardt notified Takeda pursuant to 21 U.S.C. §

355(j)(2)(B) that Wockhardt had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on June 21, 2010 and sued Wockhardt on July 28, 2010. *Takeda Pharmaceutical Company Limited et. al. v. Wockhardt USA LLC et. al.*, 10-cv-05699 (S.D.N.Y.). Wockhardt's thirty-month stay accordingly expired on December 21, 2012.

127. On or around October 2010, Wockhardt settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Wockhardt was subject to a thirty-month stay that did not expire until December 21, 2012, Wockhardt agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

128. Absent Takeda's wrongful conduct, Wockhardt would have received final FDA approval and entered the market much sooner than it did, on a date to be proved at trial.

129. Synthon Pharmaceuticals, Inc. ("Synthon") submitted ANDA 078472 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Synthon submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Synthon submitted Section viii Statements. With respect to the '777 Patent, Synthon submitted a Paragraph III Certification. Synthon thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic upon expiration of the '777 Patent on January 17, 2011. By letter dated July 30, 2010, Synthon notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Synthon had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda

received the letter on August 2, 2010 and sued Synthon on September 8, 2010. *Takeda Pharmaceutical Company Limited et. al. v. Synthon Pharmaceuticals, Inc. et al.*, 10-cv-06679 (S.D.N.Y.). Synthon's thirty-month stay accordingly expired on February 2, 2013.

130. On or around December 2010, Synthon settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Synthon was subject to a thirty-month stay that did not expire until February 2, 2013, Synthon agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

131. On November 8, 2012, the FDA awarded Synthon's ANDA tentative approval. On February 13, 2013, Synthon's ANDA received final approval and Synthon, through its exclusive licensee Breckinridge Pharmaceutical, Inc., entered the market with that product on or around that same day.

132. Absent Takeda's wrongful conduct, Synthon would have received final FDA approval and entered the market much sooner than it did, on a date to be proved at trial.

133. Zydus Pharmaceuticals USA, Inc. ("Zydus") submitted ANDA 202456 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Zydus submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Zydus submitted Section viii Statements. With respect to the '777 Patent, Zydus submitted a Paragraph III Certification. Zydus thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic as soon as possible after expiration of the '777 Patent. By letter dated

December 30, 2010, Zydus notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Zydus had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on January 4, 2011 and sued Zydus on January 14, 2011. *Takeda Pharmaceutical Company Limited et. al. v. Zydus Pharmaceuticals USA, Inc. et al.* 11-cv-00315 (S.D.N.Y.). Zydus's thirty-month stay accordingly expired on July 4, 2013.

134. On or around March 2011, Zydus settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Zydus was subject to a thirty-month stay that did not expire until July 4, 2013, Zydus agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

135. On February 13, 2013, Zydus's ANDA received final approval from the FDA. Absent Takeda's wrongful conduct, Zydus would have received earlier final FDA approval would have entered the market on a date to be proved at trial. Zydus did not push for approval before February 13, 2013 and the FDA did not grant approval before then, because the FDA's practice is not to grant approval until on or near the generic's agreed entry date where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement.

136. Absent Takeda's wrongful conduct, Zydus would have received final FDA approval and entered the market on a date to be proved at trial.

137. Apotex Corp. ("Apotex") submitted ANDA 202502 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Apotex submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the

Method-of-Use Patents, Apotex submitted Section viii Statements. With respect to the '777 Patent, Apotex submitted a Paragraph III Certification. Apotex thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic as soon as possible after expiration of the '777 Patent. By letter purportedly dated April 6, 2010, Apotex notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Apotex had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda purportedly received the letter on February 9, 2011 and sued Apotex on March 4, 2011. *Takeda Pharmaceutical Company Limited et. al. v. Apotex Corp.*, 11-cv-01514 (S.D.N.Y.). Apotex's thirty-month stay accordingly expired on August 9, 2013.

138. On or around April 2011, Apotex settled the lawsuit with Takeda. Given that the first-filers agreed to delay entry until August 17, 2012, that the first-filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Apotex was subject to a thirty-month that did not expire until August 9, 2013, Apotex agreed to a delayed but undisclosed licensed entry date.

139. Absent Takeda's wrongful conduct, Apotex would have received final FDA approval and entered the market on a date to be proved at trial.

140. Accord Healthcare, Inc. ("Accord") submitted ANDA 200044 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404 Patents, Accord submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Accord submitted Section viii Statements. With respect to the '777 Patent, Accord submitted either a Paragraph III or Paragraph II Certification. Accord thus carved out from its label all combination therapy uses and intended to come to market with a

monotherapy-use ACTOS generic as soon as possible. By letter dated August 23, 2011, Accord notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Accord had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on August 24, 2011 and sued Accord on September 12, 2011. *Takeda Pharmaceutical Company Limited et. al. v. Accord Healthcare Inc.*, 11-cv-06360 (S.D.N.Y.). Accord's thirty-month stay accordingly expired on February 24, 2014.

141. On or around October 2011, Accord settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Accord was subject to a thirty-month stay that did not expire until February 24, 2014, Accord agreed to delay entry until the earlier of February 13, 2013 or the date another generic version of ACTOS enters the market.

142. On February 13, 2013, Accord's ANDA received final approval from the FDA and Accord entered the market with that product on or around that same day. Absent Takeda's wrongful conduct, Accord would have received final FDA approval and entered the market much sooner than it did, on a date to be proved at trial. Accord did not push for approval before February 13, 2013 and the FDA did not grant approval before then, because the FDA's practice is not to grant approval until on or near the generic's agreed entry date where, as here, the generic applicant has agreed to delay entry pursuant to a settlement agreement.

143. Absent Takeda's wrongful conduct, Accord would have received final FDA approval entered the market much sooner than it did, on a date to be proved at trial.

144. Hetero USA, Inc. ("Hetero") submitted ANDA 203467 with respect to pioglitazone hydrochloride tablets, 15 mg, 30 mg, and 45 mg. With respect to the '584 and '404

Patents, Hetero submitted Section viii Statements addressing the Patents' method-of-use claims and Paragraph IV Certifications addressing the Patents' drug-product claims. With respect to the Method-of-Use Patents, Hetero submitted Section viii Statements. With respect to the '777 Patent, Hetero submitted a Paragraph III or Paragraph II Certification. Hetero thus carved out from its label all combination therapy uses and intended to come to market with a monotherapy-use ACTOS generic as soon as possible. By letter dated October 24, 2011, Hetero notified Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) that Hetero had submitted Paragraph IV Certifications to the '584 and '404 Patents' drug-product claims. Takeda received the letter on October 25, 2011 and sued Hetero on November 16, 2011. *Takeda Pharmaceutical Company Limited et. al. v. Hetero USA, Inc.*, 11-cv-08302 (S.D.N.Y.). Hetero's thirty-month stay accordingly expired on April 25, 2014.

145. On or around May 2012, Hetero settled the lawsuit with Takeda. Given that the first filers agreed to delay entry until August 17, 2012, that the first filers had 180-day exclusivity as a result of Takeda's false descriptions of the '584 and '404 Patents, confirmed by the FDA in 2010, and that Hetero was subject to a thirty-month stay that did not expire until April 25, 2014, Hetero agreed to a delayed but undisclosed entry date.

146. Absent Takeda's wrongful conduct, Hetero would have received final FDA approval and entered the market on a date to be proved at trial.

147. Accordingly, absent Takeda's false patent descriptions, the competitive response to the FDA's decision on Sandoz's citizen petition would have been drastically different.

148. Manufacturers such as DRL, Macleods, Wockhardt, Synthon, Zydus, Apotex, Accord, and Hetero—who all sent Takeda Paragraph IV notice letters only after the FDA's decision on Sandoz's citizen petition—would have instead chosen for their initial ANDA filing

to rely exclusively on Section viii. As a result, they would not have been subject to any Paragraph IV litigation with Takeda, and, not having their approvals blocked by any 30-month stay or 180-day exclusivity, they would have entered the market earlier than February 2013, and as early as January 17, 2011.

149. Manufacturers such as Teva—who at the time of the FDA's decision had a pending ANDA addressing the Patents exclusively under Section viii—would have continued to rely exclusively on Section viii, resulting in market entry earlier than August 2012, and as early as January 17, 2011.

150. Manufacturers such as Mylan, Ranbaxy, Watson, Sandoz, Torrent, and Aurobindo—to the extent they had at the time of the FDA's decision pending ANDAs with split certifications—would have chosen to amend their ANDAs to address the '584 and '404 Patents using only Section viii. To the extent any of these manufacturers had already settled their patent litigation with Takeda on terms requiring them to forego Section viii and enter in August 2012 or February 2013, they still would have been permitted to enter as soon as any other manufacturer relying on Section viii entered. Thus, absent Takeda's false descriptions, these manufacturers also would have entered the market earlier than August 2012 (for Mylan, Ranbaxy, and Watson) and February 2013 (for Sandoz, Torrent, and Aurobindo), and as early as January 17, 2011.

151. In short, absent Takeda's submission of patent information falsely describing the '584 Patent and '404 Patent as claiming the ACTOS drug product, massive generic entry would have occurred as early as January 17, 2011, and entry by any one generic manufacturer at that time would have triggered the right of other generic manufacturers to enter then as well. Additional massive entry would have occurred well before the first entry actually occurred in August 2012 and the later entry by subsequent filers actually occurred in February 2013. This

competition would have quickly driven the price of ACTOS and its generic equivalents down to near marginal cost, delivering more than $2 billion in cost savings to American consumers.

152. Takeda's conduct harmed Plaintiffs and the End-Payor Class by depriving them of the benefits of free and unfettered competition. Contrary to the purpose of the Hatch-Waxman Act, Takeda's anticompetitive conduct enabled it to: (i) delay the entry of less expensive generic versions of ACTOS in the United States and (ii) maintain a monopoly in the United States market for ACTOS and its generic equivalents.

153. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and the End-Payor Class have sustained substantial losses and damage to their business and property in the form of overcharges they paid for ACTOS and its generic equivalents, the exact amount of which will be proven at trial.

VIII. CLASS ACTION ALLEGATIONS

Plaintiffs bring this action under FED. R. CIV. P. 23(a) and (b)(3), on behalf of themselves and a class of the following similarly situated end-payors:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for ACTOS and/or its AB-rated generic equivalents in any form, other than for resale, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class"), from January 17, 2011 through and including the date that the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period").

154. The following persons and entities are excluded from each of the above-described proposed Classes:

a. Defendants and their officers, directors, employees, parent corporations, subsidiaries, affiliates, representatives and/or agents;

b. All federal or state governmental entities, except cities, towns or municipalities with self-funded prescription drug plans;

c. All persons or entities that purchased ACTOS or the AB-rated generic equivalent for purposes of resale and/or directly from Defendants or their affiliates;

d. Fully insured health care plans (*i.e.*, health care plans that purchased insurance from a third-party payer covering 100% of a plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid, in part, by a third-party payor, and whose co-payment was the same regardless of the retail purchase price;

f. Pharmacy Benefit Managers without capitation agreements; and

g. The Court, Court personnel and any members of their immediate families.

155. Members of the Class are so numerous that joinder is impracticable. On information and belief, the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

156. Plaintiffs' claims are typical of those of the Class members. Plaintiffs and Class members were damaged by the same wrongful conduct of Defendants, *i.e.*, as a direct and proximate result of Defendants' wrongful conduct, they paid artificially inflated prices for ACTOS and were deprived of the benefits of earlier and robust competition from cheaper generic versions of the products.

157. As to each of the Classes, Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, the interests of the Class members.

158. Plaintiffs are represented by counsel with experience in prosecuting class action antitrust litigation, with particular experience in class action antitrust litigation involving pharmaceutical products.

159. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class, thereby making the recovery of overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

160. Questions of law and fact common to the Class include, but are not limited to:

a. whether Takeda submitted improper patent information describing the '584 Patent and '404 Patent as purported drug-product patents covering ACTOS;

b. whether Takeda possessed market power or monopoly power over pioglitazone hydrochloride;

c. whether the law requires definition of a relevant market when direct proof of market power or monopoly power is available and, if so, the definition of the relevant market;

d. whether Defendants' above-described conduct has substantially affected interstate and intrastate commerce;

e. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and Class members; and

f. the quantum of aggregate overcharge damages to Plaintiffs and Class members.

161. Class action treatment is the superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding as a class action, including providing injured persons or entities with a method for obtaining redress for claims that could not practicably be pursued individually, substantially outweigh potential difficulties in the management of this action as a class action.

162. Plaintiffs know of no special difficulty that would be encountered in this action that would preclude its maintenance as a class action.

163. Certification of the Class is appropriate under FED. R. CIV. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual Class members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

164. Defendants' wrongful actions are generally applicable to the Class members as a whole, for which Plaintiffs seek, *inter alia*, damages and equitable remedies.

165. Absent a class action, Defendants would retain the benefits of their wrongdoing despite their serious violations of the law and infliction of harm on Plaintiffs and Class members.

IX. INTERSTATE AND INTRASTATE COMMERCE

166. At all relevant times, Takeda manufactured, promoted, distributed, and sold substantial amounts of ACTOS in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

167. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of ACTOS their generic equivalents.

168. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

169. Defendants' anticompetitive conduct also had substantial intrastate effects in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic ACTOS to end-payors inside each respective state. The complete foreclosure of generic ACTOS directly impacted and disrupted commerce for end-payors within each state (and will continue to do so).

170. During the relevant time period, ACTOS and its generic equivalents were shipped into each state and were sold to or paid for by end-payors in each state. Defendants' conduct as set forth in this Complaint had substantial effects on intrastate commerce in each state because ACTOS and its generic equivalents were sold to end-payors in each state at supracompetitive prices.

X. MONOPOLY POWER AND MARKET DEFINITION

171. At all relevant times, Takeda had monopoly power over ACTOS and its generic equivalents because it had the power to maintain the price of ACTOS at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

172. At all relevant times, a small, but significant, non-transitory price increase above the competitive level for ACTOS by Takeda would not have caused a loss of sales sufficient to make the price increase unprofitable.

173. At all relevant times, at competitive price levels, ACTOS did not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of ACTOS. Other oral Type 2 diabetes medicines are not AB-rated to ACTOS, cannot be automatically substituted for ACTOS by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to ACTOS, and thus, are not economic substitutes for ACTOS.

174. ACTOS is part of the Type 2 diabetes drug class called thiazolidinediones. Thiazolidinediones, like a few other antidiabetic classes of drugs, are often referred to as "insulin sensitivity enhancers" due to their ability to decrease the body's resistance to insulin. Unique to thiazolidinediones, however, is that they increase certain levels of proteins—those that are more sensitive to insulin—and thus are the primary means by which a patient's blood sugar levels may be lowered. Due to their differing effect within the body, thiazolidinediones are significantly unique in their efficacy, safety, and side effect profile. These attributes play a critical role in doctors' selection of the most appropriate antidiabetic for a particular patient.

175. Due to, among other reasons, doctors' perception of ACTOS's lower association with heart failure, death, and liver toxicity, ACTOS is significantly differentiated from other drugs in the thiazolidinedione class. For these and other clinical reasons, substantial numbers of doctors prefer ACTOS to other thiazolidinedione drugs (*e.g.*, Avandia (rosiglitazone)). For example, patients aged 65 and older who take Avandia (rosiglitazone) have a higher rate of death and a greater risk of heart failure when compared with similar patients taking ACTOS.

176. At all relevant times, the existence of other products designed to treat adults with Type 2 diabetes did not significantly constrain Takeda's pricing of ACTOS. At all relevant times, Takeda's price for ACTOS was at least 60% above its marginal cost of production and at least 40% above its marginal cost including marketing costs. Takeda never lowered the price of ACTOS in response to the pricing of other branded treatments for Type 2 diabetes (or the generic versions of such medications).

177. Takeda needed to control only ACTOS and its AB-rated generic equivalents, and no other products, to profitably maintain the price of ACTOS at supracompetitive levels. Only

the market entry of a competing, AB-rated generic version of ACTOS would have rendered Takeda unable to profitably maintain supracompetitive prices for ACTOS.

178. Takeda knew that entry of a generic version of ACTOS would be a uniquely significant market event. Takeda predicted that, unlike the entry of other branded treatments for Type 2 diabetes (or the generic versions of such medications), entry of generic ACTOS would take substantial unit sales from Takeda. For example, ACTOS did not lose substantial sales when generic versions of other branded Type 2 diabetes drugs entered the market at low prices. But Takeda predicted that entry of generic ACTOS would immediately cause branded ACTOS to lose well more than half of its unit sales. Likewise, the ACTOS generic manufacturers estimated that their generic versions of ACTOS would take essentially all of their sales away from branded ACTOS and few, if any, sales from other branded Type 2 diabetes drugs (or generic versions of such medications).

179. Takeda and the ACTOS generic manufacturers predicted that the competitive impact of generic ACTOS products would be substantial. Among other things, Takeda predicted that the availability of generic ACTOS would deliver well more than a billion dollars of savings to consumers.

180. At all relevant times, Takeda sold ACTOS at prices well in excess of its marginal costs and the ACTOS competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of Plaintiffs and the Class.

181. Takeda had, and exercised, the power to exclude and restrict competition to ACTOS and its AB-rated bioequivalents.

182. Takeda, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections, as well as the high cost of entry and expansion.

183. To the extent Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is oral pioglitazone hydrochloride for the treatment of adults with Type 2 diabetes (*i.e.*, ACTOS and its AB-rated generic equivalents). At all relevant times, Takeda profitably maintained the price of pioglitazone hydrochloride well above competitive levels.

184. The relevant geographic market is the United States and its territories.

185. At all relevant times, Takeda's market share in the relevant geographic market was 100%, confirming its monopoly power.

XI. MARKET EFFECTS AND DAMAGES TO THE CLASS

186. But for the anticompetitive conduct alleged above, generic competition for ACTOS would have begun as early as January 17, 2011.

187. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting ACTOS from generic competition. Takeda's unlawful actions allowed Takeda to maintain a monopoly and exclude competition in the market for ACTOS and its generic equivalents to the detriment of Plaintiffs and the members of the Class. Defendants' anticompetitive conduct delayed and impaired generic competition and unlawfully enabled Takeda to sell ACTOS without timely generic competition.

188. Typically, generic drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, end-payors rapidly

substitute generic versions of a branded drug for some or all of their purchases. As more generic drug manufacturers enter the market, prices for generic versions of a branded drug predictably plunge even further due to competition between the generic drug manufacturers, and, correspondingly, the branded drug loses even more of its market share. This price competition enables purchasers to (i) purchase generic versions of a branded drug at substantially lower prices, and (ii) purchase the branded drug at a reduced price. Consequently, branded drug manufacturers have a keen financial interest in delaying and impairing generic drug competition, which, in turn causes purchasers to experience substantial increases in costs.

189. But for Defendants' anticompetitive conduct, end-payors, such as Plaintiffs and Class members, would have paid less by (i) substituting less-expensive AB-rated generic ACTOS for the more expensive branded ACTOS, (ii) paying reduced prices on their remaining branded ACTOS purchases, and/or (iii) purchasing generic ACTOS at lower prices sooner.

190. Moreover, due to Defendants' anticompetitive conduct, other generic drug manufacturers were discouraged from and/or delayed in (i) developing and marketing generic versions of ACTOS, and/or (ii) challenging the validity or infringement of Takeda's patents in court.

191. At all relevant times during the Class Period, Plaintiffs and the Class members indirectly purchased substantial amounts of ACTOS. As a direct and proximate result of Defendants' illegal conduct, Plaintiffs and the Class members were compelled to pay, and did pay, artificially inflated prices for ACTOS and their generic equivalents. Plaintiffs and the Class members paid prices substantially greater than the prices they otherwise would have paid absent Defendants' illegal conduct because Class members: (i) were deprived of the opportunity to

purchase lower-priced generic ACTOS instead of expensive branded ACTOS, and (ii) paid artificially inflated prices for ACTOS and their generic equivalents.

192. As a direct and proximate result of Defendants' unlawful anticompetitive scheme and wrongful conduct, Plaintiffs and Class members have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for ACTOS and their generic equivalents, the exact amount of which will be proven at trial.

193. Defendants' unlawful conduct deprived Plaintiffs and Class members of the benefits of competition that the antitrust laws were designed to ensure.

XII. ANTITRUST IMPACT

194. Overcharges for pharmaceuticals at a higher level of distribution generally result in higher prices at every level below.

195. Wholesalers and retailers passed on the inflated prices of branded ACTOS and AB-rated generic ACTOS to Plaintiffs and Class members.

196. Defendants' anticompetitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

197. The inflated prices paid by Plaintiffs and Class members are traceable to, and the direct, proximate and foreseeable result of, Defendants' overcharges.

198. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for ACTOS results in higher prices at every level below. Herbert Hovenkamp, *FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE* p. 624 (1994). Professor Herbert Hovenkamp goes on to state that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." He

also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

199. Defendants' anticompetitive conduct enabled them to charge consumers indirectly and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

200. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

201. The inflated prices the members of the Classes paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme Under State Law

202. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

203. At all relevant times, Takeda possessed substantial market power (*i.e.*, monopoly power) with respect to ACTOS and its generic equivalents. Takeda possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the sale of ACTOS and its generic equivalents.

204. Takeda willfully maintained its monopoly power with respect to ACTOS and its generic equivalents, using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class members thereby. Takeda's exclusionary conduct included (i) submitting improper patent information describing the '584 Patent and '404 Patent as drug product patents for ACTOS and (ii) intentionally creating a "bottleneck" to prevent later-filing generic manufacturers from entering the market before the first filers.

205. It was Takeda's conscious objective to further its dominance of the sale of ACTOS and its generic equivalents by and through the overarching anticompetitive scheme.

206. Takeda's scheme harmed competition as alleged in detail above.

207. As a direct and proximate result of Takeda's illegal and monopolistic conduct, as alleged herein, Plaintiffs and Class members were injured.

208. By engaging in the foregoing wrongful conduct, Takeda intentionally and wrongfully maintained monopoly power over the sale of ACTOS and its generic equivalents, in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the Class.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of ACTOS in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of ACTOS in Illinois by members of the Class.

e. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of ACTOS in Iowa by members of the Class.

f. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of ACTOS in Maine by members of the Class.

g. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the Class.

h. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of ACTOS in Minnesota by members of the Class.

i. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the Class.

j. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the Class.

k. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the Class.

l. N.H. Rev. Stat. Ann. §§ 356.3, with respect to purchases of ACTOS in New Hampshire by members of the Class.

m. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the Class.

n. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the Class.

o. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the Class.

p. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the Class.

q. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of ACTOS in Puerto Rico by members of the Class.

r. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases in Rhode Island by members of the Class.

s. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the Class.

t. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by members of the Class who reside in Utah.

u. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the Class.

v. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the Class.

209. Plaintiffs and the Class members have been injured in their business or property by reason of Takeda's antitrust violations, in that Plaintiffs and the Class members (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

210. Plaintiffs and the Class members seek damages and multiple damages as permitted by law for their injuries.

SECOND CLAIM FOR RELIEF
Attempted Monopolization Under State Law

211. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

212. Takeda specifically intended to maintain monopoly power in the relevant market. It was Takeda's conscious objective to control prices and/or to exclude competition in the relevant market.

213. The natural, intended, and foreseeable consequence of Takeda's unlawful conduct was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

214. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Takeda would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

215. As a direct and proximate result of Takeda's illegal and monopolistic conduct, Plaintiffs and the Class members were harmed as alleged in detail above.

216. By engaging in the foregoing conduct, Takeda intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of ACTOS in Arizona by members of the Class.

b. Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of ACTOS in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of ACTOS in the District of Columbia by members of the Class.

d. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of ACTOS in Illinois by members of the Class.

e. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of ACTOS in Iowa by members of the Class.

f. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of ACTOS in Maine by members of the Class.

g. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of ACTOS in Michigan by members of the Class.

h. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of ACTOS in Minnesota by members of the Class.

i. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of ACTOS in Mississippi by members of the Class.

j. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of ACTOS in Nebraska by members of the Class.

k. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of ACTOS in Nevada by members of the Class.

l. N.H. Rev. Stat. Ann. §§ 356.3, et *seq.*, with respect to purchases of ACTOS in New Hampshire by members of the Class.

m. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of ACTOS in New Mexico by members of the Class.

n. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of ACTOS in North Carolina by members of the Class.

o. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of ACTOS in North Dakota by members of the Class.

p. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of ACTOS in Oregon by members of the Class.

q. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of ACTOS in Puerto Rico by members of the Class.

r. R.I. Gen. Laws §§ 6-36-5 *et seq.,* with respect to purchases in Rhode Island by members of the Class.

s. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of ACTOS in South Dakota by members of the Class.

t. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of ACTOS in Utah by members of the Class who reside in Utah.

u. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of ACTOS in West Virginia by members of the Class.

v. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of ACTOS in Wisconsin by members of the Class.

217. Plaintiffs and the Class members have been (and will continue to be) injured in their business or property by reason of Takeda's antitrust violations, in that Plaintiffs and the Class members (i) were denied the opportunity to purchase lower-priced generic ACTOS, and (ii) paid higher prices for branded ACTOS than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

218. Plaintiffs and Class members seek damages and multiple damages as permitted by law for their injuries.

XIV. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, individually and on behalf of the Class, respectfully demand judgment for the following relief:

A. Certification of this action as a class action, pursuant to Fed. R. Civ. P. 23(a), 23 and (b)(3), direction of reasonable Class notice, pursuant to by Fed. R. Civ. P. 23(c)(2), appointment of Plaintiffs as representatives of the Classes, and appointment of Plaintiffs' counsel as Class Counsel;

B. A finding that Defendants' wrongful conduct alleged herein violated the statutes set forth above;

C. Joint and several judgments against Defendants in favor of Plaintiffs and the Class;

D. Plaintiffs' and Class members' damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

E. Attorneys' fees, litigation expenses, and costs of suit; and

F. Such other and further relief as necessary to correct the anticompetitive market effects caused by Defendants' unlawful conduct, and as the Court deems just.

XV. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs, individually and on behalf of the proposed Classes, respectfully demand a trial by jury on all issues so triable.

Dated: March 12, 2018

Respectfully submitted,

s/ *Steve D. Shadowen*

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CERTIFICATE OF SERVICE

I hereby certify that on March 12, 2018 a copy of the foregoing was filed electronically. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

Dated: March 12, 2018

s/ *Steve D. Shadowen*
Steve D. Shadowen